

## Related Health System **Building Blocks**

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## STRENGTHENING PHARMACOVIGILANCE **SYSTEMS IN SWAZILAND TO IMPROVE** PATIENT SAFETY AND TREATMENT OUTCOMES



CHALLENGE Implementing comprehensive pharmacovigilance programs in resource-limited settings

Along with passive surveillance, sentinel sitebased active surveillance is a key approach to strengthening a country's pharmacovigilance (PV) and medicine safety system. As new essential medicines for HIV/AIDS and drug-resistant tuberculosis (TB) are being introduced and scaled up in resource-limited countries, monitoring adverse drug reactions (ADRs) and therapeutic effectiveness associated with these medicines is increasingly important. A well-integrated, comprehensive pharmacovigilance system is necessary for improving patient management, making evidence-based treatment decisions, and promoting rational medicine use.

Swaziland has a high burden of both HIV/AIDS and TB, and the nation's pharmacovigilance system has traditionally relied on passive surveillance mechanisms based on spontaneous

reporting. In a passive surveillance system, health professionals and others are encouraged to report adverse events, but no other active measures are used. Thus, relying on passive surveillance alone can lead to under-detection and underreporting of adverse drug events. In Swaziland, the Ministry of Health (MOH) had only been receiving about 30 adverse reaction reports per year since the passive surveillance system was implemented in 2010. This low level of reporting spurred the introduction of an active surveillance system to complement the passive system.

Pharmacovigilance is necessary for improving patient management, making evidence-based treatment decisions, and promoting rational medicine use.

### SIAPS ACTIVITIES **Introducing active surveillance measures** for HIV/AIDS and TB treatment programs

SIAPS mobilized stakeholders from the Swaziland National AIDS Program (SNAP) and the National Tuberculosis Control Program (NTCP) to introduce and implement the Sentinel Site-based Active Surveillance System for Antiretroviral and Anti-TB (SSASSA) treatment programs. SIAPS partnered with the Pharmacovigilance Unit of the MOH to create the protocol and tools for the electronic SSASSA system, and developed a patient recruitment system at HIV and TB sites.

The new system documents and quantifies incidence rates of adverse events associated with antiretrovirals (ARVs) and anti-TB medicines and determines risk factors at selected sentinel sites. In addition to collecting and compiling the type

and rate of adverse events, the SSASSA system tracks and reports data on adherence, severity of adverse events, patient demographics, and reasons for switching regimens.

The SSASSA was officially launched in 2013, and subsequently installed at five hospitals and one clinic.

SIAPS continues to support the implementation of the active surveillance system through supervisory visits to ensure data collation, causality assessments, and other patient analyses are occurring correctly. SIAPS also supports the dissemination of pharmacovigilance data from the SSASSA system at both the national and regional levels.

RESULTS Data from active surveillance help monitor medicines safety and enable data-driven decision making

Based on the most recent data from June 2013 to May 2014, a total of 956 patients have been enrolled, and 58 adverse events have been recorded. Figure 1 depicts the types of adverse events reported, the most common of which is peripheral neuropathy (26% of all events). Figure 2 illustrates adherence levels among 428 patients. as measured by timing of follow-up and medicine use. As indicated in the graph, nearly 90% of patients had a follow-up visit that was on time or early, and remembered to use their medicine.

Figure 1: Adverse events reported across six sites, June 2013-May 2014 (n=58)

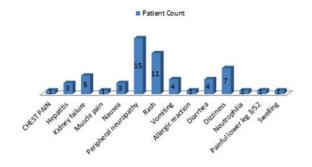
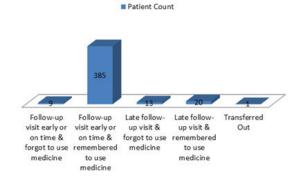


Figure 2: Patients seen for follow up and reported adherence levels across six sites, June 2013-May 2014 (n=428)



The Ministry and other relevant stakeholders are working to collect additional data and utilize this information for ongoing patient management and national-level decision making around guideline reviews, changes to treatment regimens, and adherence interventions. SIAPS continues to

support the MOH in developing Medicine Safety Watch, a quarterly newsletter designed to disseminate information on medicines safety. Copies are printed and distributed to all health facilities, and electronic copies are mailed to stakeholders.



One of the main challenges of this activity is that only four of the six sites have enrolled patients and captured data using the active surveillance system. The MOH, with support from SIAPS, is exploring the underlying constraints to using the system at these sites. In addition, data collection has not been optimal at all facilities. Recommendations have been made to modify SSASSA data fields to improve the collection of reliable data, and to update the SSASSA and the Data Collection and Analysis Tool to address compatibility issues.

The use of SSASSA in Swaziland demonstrates that active surveillance programs, which have mostly been implemented almost exclusively in industrialized countries, can be initiated successfully in resource-limited settings if system-based support and local collaboration are in place. Such an active surveillance system creates an enabling environment for regulatory decision-making and risk management planning. National bodies have provided overall leadership and governance for the implementation of these activities, and have identified and engaged other key stakeholders to contribute. Human resource capacity has also been strengthened, as evidenced by the extensive training that health care workers have received on capturing data and reporting ADRs.

# NEXT STEPS Scaling up active surveillance to monitor other medicines in additional settings

The SSASSA active surveillance system will be scaled up to monitor the safety of ARV and TB regimens throughout the country. It will also be applied to future active surveillance of other medicines, settings, and populations to prevent harmful health outcomes.

SIAPS is also currently providing support in Namibia to implement active surveillance pharmacovigilance at two sentinel HIV/AIDS sites. Drawing on lessons learned from these two countries, SIAPS plans to help implement active surveillance programs in other countries.

Development of Sustainable HIV/TB Active Surveillance System in Swaziland – Protocol and Operational Plan

Garb M. and Joshi M. 2012. Technical Assistance for the Development of Instructor's Guides for Implementing Pre-service and In-service Curricula on Pharmacovigilance in Vietnam.

**ABOUT SIAPS** | The Systems for Improved Access to Pharmaceuticals and Services (SIAPS) program works to assure access to quality pharmaceutical products and effective pharmaceutical services through systems-strengthening approaches to achieve positive and lasting health outcomes. SIAPS is funded by the US Agency for International Development (USAID) and is implemented by Management Sciences for Health. For more information, visit www.SIAPSprogram.org.



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